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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,955	04/25/2000	Yvonne E. Penfold	IMIN.P-027	8900

21121 7590 03/27/2003
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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT PAPER NUMBER

1645

DATE MAILED: 03/27/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/557,955

Applicant(s)
Penfold et al

Examiner
Patricia A. Duffy

Art Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 17, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-20 is/are allowed.
- 6) ☒ Claim(s) 2-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 12 6) ☐ Other: _____

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DETAILED ACTION

Response to Amendment

1. The amendment filed 1-17-03 has been entered into the record. Claims 12-20 are allowable, Claims 2-11 are under examination.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

New Rejections Based on Amendment

3. Claims 2-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 9, and every claim dependent thereon (2-8, 10-11), the claims are indefinite because it is unclear if the claim is directed to an assay device, a process of assaying or the particulate reagent. The claim is further confusing because the prior claim required binding of the labeled reagent in a detection and control zone. Now the claim states that the non-specific protein which "can participate". It does not require that the labeled reagent actually participate. Further the claim is not in compliance with 37 CFR § 1.75 (e), as in the case of an improvement, any independent claim should contain in the following order: (1) A preamble comprising a general description of all the elements or steps of the claimed combination which are conventional or known, (2) A phrase such as "wherein the improvement comprises," and (3) Those elements, steps, and/or relationships which constitute that portion of the claimed combination which the applicant considers as the new or improved portion.

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As to claim 5, the claim is unclear because it is unclear if the recitation is "admitted prior art" as it relates to the preamble or is meant to reconstruct the direct particulate label of the Jepson claim (i.e. "said" direct particulate label).

As to claim 6, the claim is confusing because it is unclear what limitation is applied to what portion of particulate label of claim 9. The claims still lack proper antecedent basis. Applicants should restructure the claims to recite "wherein the particle of the direct label" is first colored latex particle of a diameter less than 0.5 micron, wherein the first specific binding agent is anti-hCG murine monoclonal antibody and wherein the non-specific protein is rabbit IgG. Clear relationships back to the independent claim is necessary to interpret the assay reagents of the Jepson claim format.

As to claim 7 and 8, it is unclear if the limitation is admitted prior art or not or how it limits the independent claim in a Jepson format. Again clear antecedent basis back to the independent claim is necessary. Is applicants intending to recite "wherein the labeled reagent additionally comprises a second latex particle of the same colour as the first latex particle, wherein the second latex particle has a diameter of less than 0.5 microns and is sensitized solely with rabbit IgG and wherein the ratio of the first and second latex particles in the labeled reagent is 2:1. Claim 8 as it depends from claim 7 is still unclear how it provides for clear antecedent basis in claim 8 and claim 7.

Claim Rejections - 35 U.S.C. § 102

4. Claims 5, 9, 10 and 11 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by May et al (U.S. Patent No. 5,662,871, filed July 15, 1993, issued April 22, 1997).

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Due to the Jepson format of the claim, the limitations outside of the labeled reagent comprising a particulate direct label co-sensitized with a first specific binding reagent having specificity for an analyte and a non-specific protein which can participate in a control reaction, the following art of record is reapplied.

May et al teaches a particulate direct label co-sensitized with a first specific binding reagent having specificity for an analyte and a non-specific protein which can participate in a control reaction see column 16, lines 34-57, which teaches a coloured latex particle having an anti-alpha hCG antibody and bovine serum albumin co-sensitized on the direct particulate label and its use in a chromatographic assay (column 1, first full paragraph). As such, the prior art teaches the specific element that is defined by means of a Jepson claim to be the novel inventive contribution over the art. As such, any limitation that is not directed toward the labeled reagent comprising a particulate direct label co-sensitized with a first specific binding reagent having specificity for an analyte and a non-specific protein which "can" participate in a control reaction is not seen to limit the subject matter of the claim. Further, the recitation of "can participate in a control reaction..." is not seen to distinguish the labeled particle of the prior art as compared to the claimed particulate direct label co-sensitized with two functional reagents. The "intended use" of the reagent in an assay does not limit the product "improvement" as is now claimed in the newly recited Jepson claim format.

Status of Claims

5. Claims 2-11 stand rejected. Claims 12-20 are allowed.

Conclusion

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6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

7. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.

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March 27, 2003

Patricia A. Duffy
Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600